RECEIVED
CENTRAL FAX CENTER
MAY 06 2008

THORPE NORTH AND WESTERN™

# FACSIMILE TRANSMISSION

DATE: MAY 6, 2008 PAGE 1 OF: 13

TO: USPTO FACSIMILE NO.: (571) 273-8300

FROM: GARY P. OAKESON TRANSMITTED BY: BRENDA WISEMAN

OUR DOCKET NO.: 00015-22306

FOR: HYPOALLERGENIC METAL AMINO ACID CHELATES AND METAL AMINO ACID CHELATE-CONTAINING COMPOSITIONS

SUBJECT: REPLY BRIEF UNDER 37 C.F.R. § 41.41

---

Commissioner For Patents
PO Box 1450
Alexandria, VA 22313-1450

Dear Sir/Madam:

Attached please find a Reply Brief under 37 C.F.R. § 41.41 for Docket No. 00015-22306, Application No. 10/828,827.

Thank you. We await your confirmation of receipt.

Respectfully submitted,

Gary P. Oakeson
THORPE NORTH & WESTERN, LLP
Customer No. 20,551
Reg. No. 44266

---



www.tnw.com

8180 South 700 East • Suite 200 • Sandy, Utah 84070-0562 • 801 566 6633 • f 801.566.0750 • pallaw@tnw.com U.S. Mailing Address: P.O Box 1219 • Sandy, Utah 84091-1219

PTO/SB/21 (04-07)
Approved for use through 09/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE


# TRANSMITTAL FORM

*(to be used for all correspondence after initial filing)*

Total Number of Pages in This Submission

| | |
|---|---|
| Application Number | 10/828,827 |
| Filing Date | 4/21/2004 |
| First Named Inventor | Max R. Motyka |
| Art Unit | 1616 |
| Examiner Name | Ernst V. Arnold |
| Attorney Docket Number | 00015-22308 |

## ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☑ Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
- ☐ Proprietary Information
- ☐ Status Letter
- ☐ Other Enclosure(s) (please identify below):

Remarks

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

| | | | |
|---|---|---|---|
| Firm Name | Thorpe North & Western, LLP | | |
| Signature | | | |
| Printed name | Gary P. Oakeson | | |
| Date | 05/06/2008 | Reg. No. | 44266 |

## CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

| | | | |
|---|---|---|---|
| Signature | Brenda Wiseman | | |
| Typed or printed name | Brenda Wiseman | Date | 05/06/2008 |

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | |
|---|---|
| APPELLANT: | Max R. Motyka |
| SERIAL NO.: | 10/828,827 |
| FILING DATE: | 04/21/2004 |
| CONF. NO.: | 5229 |
| FOR: | HYPOALLERGENIC METAL AMINO ACID CHELATES AND METAL AMINO ACID CHELATE-CONTAINING COMPOSITIONS |
| ART UNIT: | 1616 |
| EXAMINER: | Ernst V. Arnold |
| DOCKET NO.: | 00015-22306 |

**CERTIFICATE OF DEPOSIT UNDER 37 C.F.R. § 1.8**

I hereby certify that this correspondence is being transmitted via facsimile to the USPTO or being deposited with the United States Postal Service with sufficient postage as first class postage in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.

5/6/08
Date of Deposit

Brenda Wiseman
Brenda Wiseman

APPELLANTS' REPLY BRIEF UNDER 37 C.F.R. § 41.41

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Mail Stop Appeal Brief – Patents

Sir:

Appellants submit this Reply Brief in response to the Examiner's Answer, mailed on March 14, 2008, in connection with their Appeal Brief, filed on December 6, 2007, which was filed in response to the final rejection of the Patent Office, mailed July 11, 2007, in the above-identified application.

STATUS OF CLAIMS

Claims 38-54 remain pending and rejected. Claim 1-37 have been canceled.

The claims on appeal in this application are claims 38-54.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The issues presented for review are:

a. whether claims 38-40, 44-46, 48-49, and 52-54 are unpatentable under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,504,055 (hereinafter "Hsu");

b. whether claims 38-40, 44-46, and 48-49 are unpatentable under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,426,424 (hereinafter "Ashmead '424");

c. whether claims 38-40, 43-49, and 52-54 are unpatentable under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,725,427 (hereinafter "Ashmead '427"); and

d. whether claims 41-42 and 50-51 are unpatentable under 35 U.S.C. § 103(a) as being obvious over Ashmead '427 in view of "Production and Utilization of Amino Acids" published in Angewandte Chemie International Edition authored by Yoshiharu Izumi, Ichiro Chibata, and Tamio Itoh (Angew. Chem. Int. Ed. Engl. 17, 176-183) (hereinafter "Izumi").

ARGUMENT

A. Examiner's Answer

The following numbered paragraphs summarize the Examiner's 103 rejections and the Examiner's response to the Appellants' arguments. The following section B addresses those arguments that have been presented by the Examiner in response to the Appellants' previous arguments. The Appellants refer the Board of Appeals to the Appeal Brief for a more complete summary of Appellants' positions, as supplemented by the present Reply Brief.

1. In rejecting claims 38-40, 44-46, 48-49, and 52-54, the Examiner alleges that Hsu teaches metal amino acid chelates. Even though Hsu does not teach hypoallergenic products or materials, the Examiner notes that "[i]t is the Examiner's position that the method of Hsu et al. is the same as that claimed in instant claim 52, i.e., it results in the same composition." See Examiner's Answer, page 4.

2. In rejecting claims 38-40, 44-46, and 48-49, the Examiner alleges that Ashmead '424 teaches metal amino acid chelates. The Examiner does not address the hypoallergenic element in this rejection.

3. In rejecting claims 38-40, 43-49, and 52-54, the Examiner alleges that Ashmead '427 teaches metal amino acid chelates. The Examiner states that "[i]t is the Examiner's position that someone had to taste the composition and report on the flavor' any subject can be susceptible to allergens upon exposure to allergens; amino acids can be purchased in pharmaceutically pure form implicitly having no allergens thus reading on the method of instant claims 43 and 52. Subjects can inherently have allergies to at least one of soy, peanuts, tree nuts, crustaceans, finfish, dairy, wheat, eggs, corn, gelatin, whey, chocolate, and strawberries." See Examiner's answer, page 6.

4. In rejecting claims 41-42 and 50-51, the Examiner alleges that Ashmead '427 in view of Izumi teaches a method of producing metal amino acid chelates other than protein hydrolysis.

5. In response to Appellants' argument that the references cited by the Examiner do not positively recite "hypoallergenic," the Examiner asserts that the compositions disclosed are hypoallergenic based on the Appellants' own definition of the term. The Examiner concludes that "the reasonable conclusion that is drawn from Appellant's own teachings is that compositions are hypoallergenic when 'care has been taken in formulation and/or production' to exclude such allergen sources []." See Examiner's Answer, page 9.

6. In response to Appellants' arguments that the cited references do not disclose or suggest the affirmative steps of determining the metal to by hypoallergenic and the amino acids to hypoallergenic, the Examiner responds that "[t]his falls in the realm of common sense." See Examiner's Answer, page 10. The Examiner further states that "[i]t is simply common sense that manufacturers of nutritional supplements adhere to *good manufacturing practice* or risk severe penalties and therefore select metals and amino acids that are free from contaminants and use good manufacturing practice in the production of such materials." See id.

7. In response to Appellants' argument regarding identifying a subject susceptible to a type of allergic reaction and formulating a metal amino acid chelate determined to be hypoallergenic to that type of allergic reaction, the Examiner states that "it remains the Examiner's position that any subject is susceptible to a type of allergic reaction" and that such steps are therefore inherent in the art. See Examiner's Answer, pages 10-11.

B. 102 Rejections of Independent Claims 38 and 46

Throughout the present prosecution, Appellants have attempted to explain the correct standard needed to establish anticipation. The Appellants have submitted anticipation case law to the Examiner and have argued that the Examiner must show each and every element in rejecting the present method claims. Additionally, Appellants have explained that the product-by-process inquiry cited by the Examiner throughout the prosecution does not apply to method claims, i.e., patentability of a method is independent of patentability of a product. Appellants have explained that a single product may be produced by a number of patentable methods. However, Appellants are unsure if the Examiner has considered this critical difference as the Examiner has maintained the present 102 rejections using the same logic in the present Examiner's Answer.

Notably, the Examiner has never argued that any of the presently cited references explicitly teach a hypoallergenic composition. Instead, at best, the Examiner is relying on inherency. As such, in order to establish a proper 102 rejection, the Examiner must show that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. However, the Examiner has not done so in rejecting the present method claims.

There are several "missing descriptive matters" in the present case for both independent method claims. For claim 38, none of the cited art teaches selecting an amino acid determined to be hypoallergenic or selecting a metal source determined to be hypoallergenic. The hypoallergenic determination is critical in providing a hypoallergenic metal amino acid chelate composition that is know to be hypoallergenic. For claim 46, none of the cited art teaches identifying a subject

susceptible to a type of allergic reaction; formulating a metal amino acid chelate by selecting an amino acid determined to be hypoallergenic and selecting a metal source determined to be hypoallergenic; or administering the hypoallergenic metal amino acid chelate composition to a subject.

To be clear, both independent claims 38 and 46 specifically require an affirmative hypoallergenic determination steps with respect to both the amino acid source and the metal source. The present specification is specific in defining the terms hypoallergenic, allergy, and allergen, so that no ambiguity arises as to the Appellants' methods and compositions. Specifically,

> "hypoallergenic" refers to compositions where care has been taken in formulation and/or production to ensure minimal instance of allergic reactions in a target subject or class of subjects. . .
> "[a]llergy" refers to an acquired and abnormal immune response to a substance or moiety of a substance (allergen) that produces an altered bodily reaction. . .
> "allergen" refers to a substance that causes manifestations of allergy, such as a protein or antigen.

See page 8, lines 12-29. Elaborating on this affirmative hypoallergenic determination, the specification states that "[d]etermining whether a composition or its source is hypoallergenic indicates that some type of evaluative step be performed." See page 10, lines 21-28. None of the references provided by the Examiner refers to any such "evaluative step" as required by claims 38 and 46.

Appellants wish to address the Examiner's arguments as presented in the Examiner's Answer. First, the Examiner has stated that "the reasonable conclusion that is drawn from Appellant's own teachings is that compositions are hypoallergenic when 'care has been taken in formulation and/or production' to exclude such allergen

sources []." See Examiner's Answer, page 9. Additionally, in response to the lack of teaching of affirmative hypoallergenic determination steps, the Examiner has stated that "[t]his falls in the realm of common sense" and that "[i]t is simply common sense that manufacturers of nutritional supplements adhere to *good manufacturing practice* or risk severe penalties and therefore select metals and amino acids that are free from contaminants and use good manufacturing practice in the production of such materials." See Examiner's Answer, page 10.

These points have been previously argued in Appellants' Appeal Brief. With respect to the hypoallergenic definition, the Examiner has focused on the phrase "where care has been taken" in stating "[i]t is the Examiner's position that care has been taken in the formulation of the metal amino acid chelates of the cited references such that the metal amino acid chelates would be substantially free of impurities (for example allergens) that could potentially interfere with the sensitive types of analysis performed on the metal amino acid chelates." See Final Office Action dated July 11, 2007, pages 9-10.

However, the Examiner has taken the phrase "care has been taken" out of context. Appellants have clearly defined that care has been taken "to ensure minimal instance of allergic reactions in a target subject or class of subjects." Such is not the case with the present cited references. There is simply no disclosure in any of the references that ensure a minimal instance of allergic reactions. In fact, as previously discussed, none of the references mention hypoallergenic materials or hypoallergenic compositions in any context. Again, it is noted that the method claims produce chelate compositions, and not the individual chelate molecule. In practicality, a chelate molecule does not exist in a vacuum, but rather, many chelate molecules are commingled with unreacted starting material and other material that leads to allergic

reaction. This is particularly true with amino acids, as they are typically prepared using proteins, which are notorious allergens. By selecting source material to begin with that is substantially devoid of such allergens, amino acid chelate compositions can be prepared that do not illicit allergic reactions in susceptible subjects. Again, it is the method that is being claimed, and the composition is really only relevant as to define what the method prepares, i.e. a hypoallergenic composition which includes amino acid chelates

Appellants wish to further elaborate on this point using a commonly used hypoallergenic product (this was submitted to the Examiner during prosecution). Baby formula is produced by a number of companies including Similac. In accordance with the Examiner's logic, Appellants submit that Similac takes great care in the manufacturing of its products. However, Similac offers various forms of its baby formula including a regular formula, Similac Advance Infant Formula, and a hypoallergenic formula, Similac Alimentum Hypoallergenic Formula. See http://welcomeaddition.com. Such formulations are not interchangeable. As such, Appellants submit that the mere ability to be consumed by a human or the fact that care is taken in production is not enough to ensure a hypoallergenic composition. Furthermore, Appellants stress that merely taking care in producing and/or manufacturing a product is not enough to qualify under Appellants' hypoallergenic definition. Appellants contend that the Examiner is attempting to take this one phrase from Appellants' hypoallergenic definition and use it out of context.

Second, in response to Appellants' argument regarding identifying a subject susceptible to a type of allergic reaction and formulating a metal amino acid chelate determined to be hypoallergenic to that type of allergic reaction, the Examiner states that "it remains the Examiner's position that any subject is susceptible to a type of

allergic reaction" and that such steps are therefore inherent in the art. See Examiner's Answer, pages 10-11.

Appellants have also addressed this point in Appellants' Appeal Brief. In short, Appellants submit that allergic reactions are unique and specific and that the Examiner's overly broad statement is incorrect. The fact that a person may be allergic to any given substance is not a substitute for "identifying a subject susceptible to a type of allergic reaction." As such, Appellants have recited an element not taught in any of the presently cited references. Additionally, Appellants note that as the references never identified subjects susceptible to an allergic reaction, the references cannot teach the element of administering a hypoallergenic metal amino acid composition to such a subject.

Additionally, the Examiner's use of inherency in this instance is misplaced. In order for inherency to be properly utilized, the Examiner must establish that the missing element is necessarily present. However, the Examiner has not established that an individual is necessarily allergic to every possible allergen or that the present method steps would be necessarily present in every manufacturing process. As such, a proper 102 rejection has not been made. Furthermore, note that the claim language of the method requires determination steps to make sure materials used to make the composition are hypoallergenic. These evaluative steps are wholly missing from the prior art cited.

As the present claims contain elements not taught in any of the cited references, alone or in combination, Appellants respectfully request that the Board overturn the present rejections.

## CONCLUSION

Appellants respectfully submit that the claims on appeal set forth in the Appendix of Appellants' Appeal Brief are patentably distinct from the asserted prior art references. Particularly, none of the asserted references, or combinations of references, teach each and every element of the claimed invention.

For these reasons, Appellants respectfully request that the Board of Appeals reverse the rejections and remand the case to the Examiner for allowance.

Please charge any fees except for Issue Fee or credit any overpayment to Deposit Account No. 08-2025.

Dated this 6th day of May, 2008.

Gary P. Oakeson
Attorney for Appellant
Registration No. 44,266

THORPE NORTH & WESTERN, LLP
8180 South 700 East, Suite 350
Sandy, Utah 84070
(801) 566-6633